



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500, MSC 6910  
Bethesda, Maryland 20892-6910  
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500  
Bethesda, Maryland 20817  
Telephone: (301) 496-7163  
Facsimile: (301) 480-3387

May 24, 2022

Re: Animal Welfare Assurance  
A3823-01 [OLAW Case 10C]

Dr. Mary Dickinson  
Vice President and Dean of Research  
Baylor College of Medicine  
One Baylor Plaza, BCM335  
Houston, TX 77030

Dear Dr. Dickinson,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 20, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Baylor College of Medicine. According to the information provided, OLAW understands that 10 mice were being bled retro-orbitally without anesthesia, which is contrary to what had been approved in the protocol. The mice were reportedly in good condition following the procedure.

The corrective actions consisted of retraining the laboratory staff, amending the protocol to add a topical anesthetic, enhancing communication and animal monitoring within the laboratory, placing the laboratory under enhanced post-approval monitoring, and retraining and counseling the laboratory staff. Future noncompliance may lead to escalating sanctions.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the Institutional Animal Care and Use Committee to comply with the PHS Policy.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.  
Deputy Director  
Office of Laboratory Animal Welfare

cc: IACUC Contact



A3823-10C

OFFICE OF RESEARCH

One Baylor Plaza, BCM310  
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**CONFIDENTIAL**

May 20, 2022

Brent Morse, DVM, DACLAM  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
olawdco@mail.nih.gov

RE: Assurance #D16-00475

Dear Dr. Morse,

As Institutional Official for Baylor College of Medicine (BCM), I have the duty to inform you of our Institutional Animal Care and Use Committee's (IACUC) recent finding in animal research after an assessment of the following protocol:

**Protocol:** AN-6407: Intratumoral Heterogeneity and Breast Cancer Progression

**Species:** Mice

**Funding Sources:** National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) F31-DK127543 and Non-PHS funding

For this investigator's first incident of this nature, the IACUC determined that the following finding constituted *serious noncompliance*<sup>1</sup> with the federal regulations:

**Blood collection procedure without anesthesia**<sup>11</sup>

*02/24/22 –Retro-orbital procedure without anesthesia*

During routine health evaluations in a central animal facility, a clinical veterinarian observed a researcher collecting blood from mice via the retro-orbital route without anesthesia. The IACUC approved protocol requires isoflurane anesthesia for this method. Upon inquiry, it was found that 10 mice had blood collected in this manner. All mice recovered without incident and were noted to be in good condition.

*05/10/22 – Determination, review and approval of the corrective action plan at a fully convened IACUC meeting*

To protect the welfare of animals and prevent future recurrence, the IACUC required following corrective actions:

1. The Attending Veterinarian requested that the laboratory members attend a hands-on refresher training in proper collection of blood via the retro-orbital route before continuing any additional blood collections.

<sup>1</sup> PHS Policy IV.F.3.a: "The IACUC, through the Institutional Official, shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to: a. any serious or continuing noncompliance with this Policy;"

<sup>11</sup> PHS Policy IV.B.7: "As an agent of the institution, the IACUC shall with respect to PHS-conducted or supported activities review and approve, require modifications in (to secure approval or withhold approval) of proposed significant changes regarding the use of animals in ongoing activities"

2. The Principal Investigator (PI) submitted an amendment to add an additional topical anesthetic for the retro-orbital procedure, as recommended by the Attending Veterinarian, which was reviewed and approved by the IACUC.
3. The PI provided a comprehensive oversight plan to enhance monitoring of all animal related procedures described in the IACUC approved protocol. The plan includes weekly laboratory meetings to discuss compliance and improvements, consistent review of all approved protocols by laboratory members and enhanced internal communication processes and on-boarding training.
4. Two comprehensive Post-Approval Monitoring (PAM) reviews focused on conduct of approved procedures and drug regimens described in the protocol will be conducted within the next six months.
5. All research personnel are required to complete the interactive training session "Top 10 Pitfalls and How to Avoid Them."
6. The Compliance Associate will attend three laboratory meetings to discuss compliance oversight and general non-compliance prevention.
7. If compliance with the IACUC approved plan or the increased oversight is not maintained, there will be escalating punitive corrective actions including, but not limited to suspension of all surgical privileges.

This finding of non-compliance does not appear to pose any potential or actual effect on costs related to this PHS-supported research.

This notification will also be sent to AAALAC International; National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and non-PHS funding sources according to the terms and conditions of the award.

Please do not hesitate to contact me if you have any questions.

Sincerely,

(b) (6)

Mary E. Dickinson, Ph.D.  
Sr. Vice President and Dean of Research  
Institutional Official  
Baylor College of Medicine

cc: Principal Investigator  
Department Chair  
Research Compliance Services files

**Wolff, Axel (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, May 23, 2022 7:05 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: OLAW Reports- Assurance D16-00475

Thank you for these reports, (b) (6) We will send responses soon.

Axel Wolff, M.S., D.V.M.  
Deputy Director, OLAW

**From:** (b) (6)  
**Sent:** Friday, May 20, 2022 5:41 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** (b) (6)  
**Subject:** [EXTERNAL] OLAW Reports- Assurance D16-00475

Dear Dr. Morse,

Please find the attached notifications of research non-compliance as determined by our IACUC, and sent on behalf of Dr. Mary Dickinson, Institutional Official.

Please feel free to contact me if you have any questions.

Thank you,

(b) (6)